Remarks

Claim 19 has been amended herein by deleting the last two of the three elements being claimed.

Claims 20 and 29 have been canceled herein.

Response to Objections to Claim 20

Applicants have canceled claim 20, therefore, the objection as to claim 20 is now moot. Applicants respectfully request that the objection as to claim 20 be withdrawn.

Response to 112, first paragraph, enablement rejection

Claims 19, 20, and 29 stand rejected as allegedly lacking enablement. Applicants traverse for the following reasons.

Applicants note that claims 20 and 29 has been canceled herein, therefore the rejection as to these claims is now moot. Applicants respectfully request that the rejection as to claims 20 and 29 be withdrawn.

Claim 19, as rejected by the Examiner, recited:

> "A purified or recombinant polypeptide comprising
>
> the amino acid sequence of SEQ ID NO: 16;
>
> an amino acid sequence that differs from SEQ ID NO: 16 by one to twenty conservative amino acid substitutions; or
>
> an amino acid sequence that differs from SEQ ID NO: 16 by a single mutation, wherein the single mutation represents a single amino acid deletion, insertion or substitution."

Claim 19 has been amended herein by deleting the two elements: "an amino acid sequence that differs from SEQ ID NO: 16 by one to twenty conservative amino acid substitutions; or an amino acid sequence that differs from SEQ ID NO: 16 by a single mutation, wherein the single mutation represents a single amino acid deletion, insertion or substitution."

As amended, claim 19 now recites:

> A purified or recombinant polypeptide comprising
>
> the amino acid sequence of SEQ ID NO: 16.

Applicants respectfully submit that claim 19 as amended is enabled by the specification as filed and that the rejection as to claim 19 is now moot. Applicants request that the rejection as to claim 19 be withdrawn.

Response to 112 indefiniteness rejection of Claim 20

Claim 20 has been canceled herein, therefore, the rejection as to claim 20 is now moot. Applicants respectfully request that the rejection as to claim 20 be withdrawn.

Response to 102 rejection-

The Examiner has again rejected claims 19, 20, and 29 as allegedly anticipated by U.S. 2002/0102604 (Edwards et al.) under 35 U.S.C. § 102(e). The Examiner asserts that SEQ ID NO:266 of Edwards is the sequence of the instantly claimed SEQ ID NO:16 and that it is antigenic. Applicants note that claims 20 and 29 have been canceled herein, therefore the rejection as to these claims is now moot.

Applicants traverse the rejection for the following reasons.

Applicants also note that Examiner considered a previous 1.131 Declaration to be invalid for failure to include all inventors. To that end, a new 1.131 Declaration is submitted herewith by all inventors of this application. Further provided is the appendix as submitted previously, as well as the curriculum vitaes of each inventor. All previous arguments are provided below.

Submitted herewith under 37 C.F.R. § 1.131 is a Declaration by Zhonglin Hao, John C. Herr, Friederike L. Jayes, Jagathpala Shetty, and Michael J. Wolkowicz, all of the inventors of the present invention, asserting that the presently claimed invention was invented before Edwards et al. was filed, asserts and verifies that the Edwards application, which claims the benefit of provisional application filed December 8, 1999, was not filed before the instant invention for patent by the Applicants and therefore cannot anticipate the presently claimed invention under 35 U.S.C. § 102(e).

The documentation provided with the Declaration comprises 68 photocopied pages of the laboratory notebook of one of the co-inventors, Dr. Jagathpala Shetty, who performed much of the work of the present application. The 68 pages were all dated at the time of data entry and are

labeled as Exhibits 1 through 68. All of the laboratory notebook pages also indicate the name of the person entering the data, namely Jagathpala Shetty. The pages are dated from August 12, 1999 to December 18, 1999. The invention disclosure was then prepared by the Applicants and submitted to the University of Virginia Patent Foundation. A provisional patent application was then prepared and filed on January 19, 2000. Therefore, the entire process of identifying the protein called C58, isolating it, sequencing it, performing bioinformatic analyses, protein expression and northern blot analyses, was performed from August 12, to December 18, 1999. The data were then compiled, an Invention Disclosure was prepared and submitted to the University of Virginia Patent Foundation, and a patent application was prepared and filed within a month of the last dated laboratory notebook page.

Examiner is reminded that the present application is a Divisional application and that two other proteins were prosecuted in the parent application (now issued) encompassing the peptide of SEQ ID NO:2 and the nucleic acid sequence encoding SEQ ID NO:2, and another active Divisional application encompassing SEQ ID NO:9. All of the work encompassing the various proteins was occurring simultaneously and was included in the provisional application.

The progress of the experiments related to identifying the sequence of the peptide named C58, which has the sequence of SEQ ID NO:16, will be summarized below to demonstrate when the sequence was first discovered and to demonstrate diligence in completing the invention. However, it should be noted that the complete nucleotide and amino acid (SEQ ID NO:16) sequences of C58 were first demonstrated in the laboratory notebook of Dr. Shetty on October 5 and 6, 1999 on pages 82-84 (Exhibits 35-37).

The first page of evidence supplied with the Declaration (Exhibit 1; page 39 of the notebook, dated August 12, 1999) has a copy of an image of a two-dimensional gel which is labeled with numbers to identify locations of various proteins which were partially sequenced on August 11, 1999. including C58 (the name of the protein comprising SEQ ID NO:16). The spots had been cored from the gel, subjected to tryptic digests, and subjected to microsequencing, the results of which are indicated in Exhibit 2, dated August 15, 1999. Exhibit 2 demonstrates the four peptide tryptic digest components of spot/band C58.

Exhibit 3 (page 42 of the notebook, dated August 15, 1999) depicts the use of an EST chosen based on the tryptic digests.

Exhibits 4 to 34 (comprising laboratory notebook pages 43, 48, 50-54, 56-75, and 77-80, respectively; dated August 26 to September 25, 1999), demonstrate a series of experiments and data involving further preparation and isolation of the C58 nucleic acid and peptide sequences. Exhibit 4 demonstrates the PCR strategy using the EST and Exhibit 5 demonstrates the sequence of the PCR-derived EST partial sequence for C58. Exhibit 6 (page 50, dated September 7, 1999) summarizes the cloning of C58 and the beginning of several weeks work of screening the C58 library (Exhibits 6 to 79; dated September 7, 1999 to September 30, 1999).

A nucleic acid sequence was obtained and disclosed in Exhibit 35 (page 82 of the notebook, dated **October 5, 1999**). The sequence for the nucleic acid encoding the amino acid sequence of SEQ ID NO:16 (C58 protein) included the ORF of the sequence. The sequence was examined and Exhibit 37 (page 84 of the notebook, dated **October 6, 1999**) presents the deduced 124 amino acid residue sequence of SEQ ID NO:16.

Therefore, it can be seen that the nucleic acid sequence encoding SEQ ID NO:16 was obtained by **October 5, 1999,** and at that point the nucleic acid sequence was capable of being used to deduce the amino acid sequence, which amino acid sequence (i.e., SEQ ID NO:16) was indeed demonstrated on Exhibit 37, dated **October, 6, 1999**. These two dates indicating the C58 sequences are much **earlier** than the December 8, 1999 filing date of the Edwards provisional application.

Next, a series of bioinformatic analyses were performed to compare the new sequences to other sequences known in the art and to further characterize the protein. Then, a series of experiments and analyses were performed to ensure that the complete protein had been isolated and sequenced, expression vectors were prepared and analyzed, and cells were transformed with the expression vectors and analyzed (see Exhibits 38-52, performed until November 23, 1999). For example, Exhibit 52 (the carbon copy page of page 100, with a sequence pasted in; dated November 23, 1999), demonstrates the sequence alignment of C58 with proteins of the Ly6/UPAR family of proteins.

Exhibit 53 is a copy of page from a new notebook (page 1, dated November 29, 1999) where a series of experiments analyzing protein expression from the bacterial vector were begun. These experiments are illustrated in Exhibit 53 to Exhibit 63 (comprising notebook pages 1-6, and 9-13, respectively; dated November 29, 1999 to December 15, 1999).

Next, a series of experiments were performed to verify that the newly discovered C58 protein, which was discovered in testis, was indeed a testis specific protein. To that end, a series of probes and reagents were prepared and Northern blot analyses were performed, finding testis specific expression of C58 (see Exhibits 64 to 68, comprising notebook pages 14-18, respectively, dated December 15 to December 18, 1999).

The C58 experiments performed to that date (December 18, 1999) were then included as part of an invention disclosure, along with the results of two other proteins. The invention disclosure was submitted to the University of Virginia Patent Foundation, reviewed, and prepared and filed as a provisional patent application on January 19, 1999. Thus, it can be seen that from the time of the last C58 experiment included in the application, the time required to prepare and submit the invention disclosure and prepare and file a provisional patent application was only one month. These acts all indicate diligence in inventing, reducing to practice, and filing an application based on the three proteins which were included in the original provisional application.

Based on the description provided above, the 37 C.F.R. § 1.131 Declaration provided by the inventors indicating the veracity of the statements above, the evidence provided with the Declaration in the form of dated copies of the laboratory notebook of inventor Dr. Jagathpala Shetty, assert that the present invention was clearly not anticipated by Edwards et al. under 35 U.S.C. § 102(e). Therefore, Applicants respectfully request that the anticipation rejection as to amended claim 19 be withdrawn.

Applicants respectfully submit that based on the arguments presented above, amended claim 19 is in condition for allowance.

Conclusion

If the Examiner believes that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at (434) 243-6103.

Respectfully submitted,

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Rodney L. Sparks
Registration No. 53,625
University of Virginia Patent Foundation
250 West Main Street, Suite 300
Charlottesville, VA 22902
Telephone: (434) 243-6103
Fax: (434) 924-2493